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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/462,148	06/05/95	FALK	R P-0800(0)-2

EXAMINER

12M1/0303

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ART UNIT	PAPER NUMBER
1211	5

DATE MAILED: 03/03/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause U.S. the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) the 11,119-121 and 184-186 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 11, 119-121 and 184-186 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

PTOL-326 (Rev. 9/96)

★ U.S. GPO: 1996-404-498/40517

The specification is still objected to because it is presented on both sides of the paper. Substitute specification has not been received.

Claims 11, 119, 121, 184 and 186 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terminology "selected from" (claims 11, 119 and 184) is an improper markush terminology. Such terminology as "selected from the group consisting of" can be used to overcome the above rejection.

Claims 11, 119-121 and 184-186 still stand rejected under 35 U.S.C. 103(a) as being unpatentable over Della Valle et al (U.S. Patent No. 4,736,024) in combination with Lowry (U.S. Patent No. 4,900,550) and Karanewskyl (U.S. Patent No. 4,711,884) for the reqsons set forth in the Office Action of June 18, 1996.

Applicant's arguments filed December 12, 1996 have been fully considered but they are not persuasive.

Applicants contend that Della Valle et al patent does not teach the claimed dosage but teaches very small dosages containing less than .2 mg. of HA per drop applied to the cornea of the eye together with the medicine. This argument has not been found persuasive. In column 2, lines 52-68, Della Valle et al teach that the combination of HA and a drug can also be used in dermatology and disesases affecting the mucuous mwmbrane. Della Valle et al further teach concentration of such solutions within ample limits , for example, betwewen 0.01 and 75% both

for each of the components taken separately, and for their mixtures and salts (column 9, lines 1-16). Thus, the teaching by Della Valle et al is not limited to the use in ophthalmology and also covers a broad range of concentrations and dosages.

The declaration by Torvard C. Laurent has been considered but has oit been found persuasive. The declaration states that prior to the instant invention, it was not known that hyaluronic acid potentiates the action of the drugs. However, the declartion fails to present any data showing that hyaluronic acid potentiates the effect of the drugs encompassed by the instant application.

The declaration by Joseph Robert Emmott Fraser has been considered but has not been found persuasive. The delaration states that the instant invention uses dosages of HA much larger than expected and that the instant invention relates to the use of HA for targeting the medicines for better performance. However, this declaration fails to provide any data showing the potentiating effect of HA on the drug encompassed by the instant claims.

The declarations by Ian Constable , Eva Turley, Stefan Gustafson and Adrian Moore have also been considered but have not been found persuasive. Again the declarations fail to present any data showing that HA enhances the ability of known medicines. Therefore, the claimed methods and compositions are still deemed prima facie obvious over the art of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to Elli Peselev at telephone number (703) 308-4616.

ELLI PESELEV
PRIMARY EXAMINER
GROUP 1200